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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,975	08/26/2003	Dusan Miljkovic	100700.0016US1	4147

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,975	MILJKOVIC, DUSAN	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a dietary supplement containing a carbohydrate/boron complex combined at least one of calcium, magnesium and vitamin D, classified in class 426, subclass 74.

II. Claims 12-17, drawn to a method of increasing steroid concentration in a human comprising providing a carbohydrate/boron complex, classified in class 424, subclass 657.

III. Claim18-20, drawn to a method of marketing a dietary supplement by providing printed information, classified in class 283, subclass 67.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using the product as evidence by the two methods, one of increasing steroid levels in humans and the other of marketing a dietary supplement.

Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in

scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function or effect in that the Invention I the composition requires administration to the human of a boron/carbohydrate complex and Invention II does not require administration to a human of any dietary supplement, does not require that a human be given the boron/carbohydrate complex and requires dissemination of printed information; for the same reasons the inventions do not overlap and are not obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be an undue burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be an undue burden on the examiner if restriction is not required because the inventions require a different field of search in that group I does not require search of a method for increasing steroid concentration or marketing (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be an undue burden on the examiner if restriction is not required because the invention III (marketing) has acquired a separate status in the art from I (dietary supplement) and II (method of increasing steroid concentration) due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Martin Fessenmaier on 9/25/2006 a provisional election was made without traverse to prosecute the invention of group II, claims 12-17. Affirmation of this election must be made by applicant in replying to this Office action. During the course of prosecuting the method claims 12-17, the Examiner determined that prosecution of the same constituted a sufficient search of the composition claims. As such, the restriction requirement between Groups I and II is withdrawn. Thus, claims 1-17 will be prosecuted accordingly. Claims 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-9, 11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Miljkovic (US Pat. 5,962,049)

Miljkovic expressly discloses a food containing at least 0.5 mg of boron in containing a calcium or magnesium fructose boron complex in which the boron-ligand association constant is at least 250 falling within the scope of applicant's claims (Claims 1, 10, 19, 20). The amounts of

carbohydrate-boron complex are defined by the effect when administered, however, the amount of boron disclosed in the prior art falls within the scope of the effective amounts as the Specification indicates that amounts of the carbohydrate-boron complex can be at least 0.1 mg and less than 0.1 mg (Specification, page 10, lines 13-24). As such, the food supplement which provides at least 0.5 mg of boron in the form of a carbohydrate-boron complex falls within the scope of the claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miljkovic (US Pat. 5,962,049) in view of Naghii et al. (Abstract), Nielsen and Volpe et al. (Abstract)

Miljkovic discloses a food containing at least 0.5 mg of boron in containing a calcium or magnesium fructose boron complex in which the boron-ligand association constant is at least 250 falling within the scope of applicant's claims (Claims 1, 10, 19, 20). It is disclosed that boron offers significant benefits with respect to bone and joint health and that the optimum daily of intake is about 2-3 mg/day (Column 1, lines 23,24, 35,36). It is disclosed that the sugar-boron compounds can be included in pharmaceutical preparations, including with suitable excipients, binders, carriers and other compounds as known in the pharmaceutical arts, including vitamin pills and other forms of supplements, with the dosage providing about 0.01 mg/day/dose to about 10 mg/day/dose or more of boron (Column 5, lines 13-22, Column 6, lines 1-5).

Naghii et al. disclose that supplementation of 10 mg of boron per day for 4 weeks significantly increased plasma estradiol concentrations and there was a trend for plasma testosterone levels to be increased (Abstract).

Neilsen disclose an experiment in which patients were fed a boron-low diet for 63 days and then supplemented with 3 mg/day boron for 49 days and that when compared serum 25 hydroxycholecalciferol was lower in the depletion period compared to the repletion period (Page 59). It is disclosed that the reason for estrogen therapy is to prevent calcium and bone loss which can lead to osteoporosis (page 62).

Volpe et al. disclose that the role of boron in bone metabolism and increasing bone density is most likely to be associated with interactions with other minerals and vitamins, such as calcium, magnesium and vitamin D (Abstract).

The prior art discloses a carbohydrate-boron complex having a ligand affinity of greater than 250, including a calcium or magnesium fructose boron complex and that boron is important in bone and joint health. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose combining with Vitamin D, formulation as a tablet or capsule or a method of increasing steroid concentration in a human with the carbohydrate-boron complex. The prior art amply suggests the same as the prior art discloses that boron supplementation decreases bone loss, increases serum levels of estradiol, testosterone and 25-hydroxy cholecalciferol, that estrogen therapy decrease calcium and bone loss, that boron's effect on bone metabolism is likely due to interactions with calcium, magnesium and vitamin D and that the carbohydrate-boron complex can be in various pharmaceutical forms, including vitamin pills. As such, it would have been well within the skill of and one of ordinary skill in the

art would have been motivated to modify the prior art as above with the expectation that the carbohydrate-boron complex would be effective in increasing steroid concentration in humans, that increasing serum estradiol would increase bone density, that boron's effect on bone metabolism would be facilitated by the addition of calcium, magnesium and vitamin D and that the dietary supplement can be in any form desired, including pills and mixtures with suitable excipients, binders and carriers and other compounds included as known in the pharmaceutical arts.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
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October 2, 2006

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